K083600

FEB 19 2009

Executive Summary of

POWDER-FREE VINYL EXAMINATION GLOVES, CLEAR (NON-COLORED)

Submitter's Name	Quantum Co., Ltd
Submitter's address	No. 2-3-18 Hua Sheng Yuan Park, Linzi, Shandong 255410 China
Submistter's Telphone Number	+86-533-7480087
Submiter's Fax Number	+86-533-7480085
Name of Contact Person	Lijuan Wang
Date of Preparation	November 20th, 2008
Device Description	The Powder-free vinyl Examination glove, clear (Non-colored) is disposable device made PVC resin and plasticizers (DINP), Ca-Zn stabilizer, TXIB into film, coated with Polyurethane to facilitate donning and it intended to be worn on the hand of finger(s) for medical purpose to provide a barrier against potentially infectious materials and other contaminants.
Legally Marketed Device To Which Equivalency is Being Claimed **Predicate Device**	Powder-free vinyl Examination glove, clear (Non-colored) is described in the 510 (k) notification are substantially equivalent to the Class I patient examination gloves, Vinyl, 80LYZ coated with Polyurethane dusting powder, that meets the current ASTM D5250-06 "Standard Specification for Polyvinyl Examination Gloves for Medical Application" **A) K070149** POWDER-FREE VINYL PATIENT EXAMINATION GLOVES, MANUFACTURED BY: WUXI SHENZHOU PLASTIC PRODUCTS CO., LTD. **B) K073193** POWDER-FREE VINYL PATIENT EXAMINATION GLOVES

Summary of Technological Characteristics Compared to the Predicate Device **Performance testing report**	MANUFACTURED BY: SHIJIAZHUANG PROSPEROUS PLASTIC CO., LTD. Technological characteristics. Gloves are made from PVC and DINP compound and the initial products are powder free vinyl examination gloves, clear (non-colored).
Intended use of the Device	A Powder-free vinyl Examination glove, clear (Non-colored) is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.
Brief Discussion of Nonclinical Tests	Testing is performed as per ASTM D5250-06 and 21 CFR 800.20, gloves meet all the current Specifications listed under the ASTM D5250-06 Standard Specification for Vinyl Examination Gloves. Primary Skin Irritation testing in the rabbit and delayed contact Sensitization testing in the guinea pig indicate no irritation or sensitization.
Brief Discussion of Clinical Tests	No new clinical tests were conducted under this 510 (k)
Conclusions Drawn for the Non clinical and Clinical Tests	Non-clinical Laboratory and animal data indicate that the pre-powdered vinyl products meet all performance and biocompatibility requirements.
Other Information Deemed Necessary by FDA	Non Applicable

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 19 2009

Ms. Lijuan Wang
Operation Manager
Quantum Company, Limited
Number 2-3-18 Hua Sheng Yuan Park Linzi
Shandong 255410
CHINA

Re: K083600
Trade/Device Name: Powder-Free Vinyl Examination Gloves, Clear (Non-Colored)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYZ
Dated: February 1, 2009
Received: February 4, 2009

Dear Ms. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Attachment I

Indications for Use

510(k) Number (if known): K083600

Device Name: Powder-Free, Vinyl Examination Gloves, Clear (Non-Colored)

Indications for Use:

Powder-free vinyl Examination glove, clear (non-colored) is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Yours faithfully

Ms. Lijuan Wang
Operation Manager
Date: Jan 29, 2009

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083600